IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 9166

Bartle, J. November 20, 2013

Melanie L. Groce ("Ms. Groce" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she met her burden of proving that her claim was not based, in whole or in part, on any intention material misrepresentations of fact.[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Howard L. Brazil, M.D., F.A.C.C. Based on an echocardiogram dated June 28, 2002, Dr. Brazil attested in Part II of claimant's Green Form that Ms. Groce suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings,

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(...continued)
for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $522,266.[3]

In the report of claimant's echocardiogram, Dr. Brazil stated that Ms. Groce had "moderate mitral regurgitation ... with a regurgitant jet area to left atrial area of 25%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brazil also found that Ms. Groce's left atrium measured 5.8 cm in the supero-inferior systolic dimension, but he did not note his measurement of her left atrium in the antero-posterior systolic dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b)ii). In addition, Dr. Brazil determined that Ms. Groce had an ejection fraction of 55%. An ejection fraction is considered reduced for purposes of a mitral

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3. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors necessary for a Level II claim.

valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In January, 2004, the Trust forwarded the claim for review by Steven A. Fein, M.D., F.A.C.P., F.A.C.C., F.A.H.A., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Fein determined that there was a reasonable medical basis for Dr. Brazil's findings that Ms. Groce had moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.

Based on Dr. Fein's findings, the Trust issued a post-audit determination awarding Ms. Groce Matrix Benefits. Before the Trust paid Ms. Groce's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Groce's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new

post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Ms. Groce's claim, this court approved, on November 22, 2006, Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Ms. Groce elected to opt-out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Ms. Groce's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of Ms. Groce's claim.[4] As stated in his March 1, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> In Ms. Groce's study, the use of high color gain, a decreased Nyquist setting, and color pixels dominant over anatomy as well as the selection of a jet of short duration and the undermeasurement of the left atrial area are the result of deliberate choices and conduct engaged in by the sonographer performing this

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4. In November, 2004, the Trust had provided Ms. Groce with an "Expert Report" signed by Dr. Kisslo pursuant to Paragraph 11 of PTO No. 3883. In that report, Dr. Kisslo opined that "[t]he persons responsible for conducting the study and rendering a diagnosis misrepresented the size of Ms. Groce's alleged regurgitant jet by inflating and distorting the image of the jet through improper use of excessive color gain and a low Nyquist setting."

> study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated the appearance of regurgitation, jet duration or RJA/LAA ratio. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. Groce has only trivial mitral regurgitation--not moderate mitral regurgitation as claimed by the Attesting Physician. There is no reasonable medical basis for a finding of moderate mitral regurgitation based on this study.[5]

Thus, notwithstanding Dr. Fein's findings at audit, the Trust rescinded its prior post-audit determination letter and issued a new post-audit determination denying Ms. Groce's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. Groce contested this adverse determination.[6] In contest, Ms. Groce argued that her echocardiogram was performed in a manner consistent with the standards set forth in the Settlement Agreement. In support, claimant submitted affidavits from Dr. Brazil; Lynda F.

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5. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Groce's claim.

Lollar-Goldstein, the Registered Cardiovascular Technologist who performed Ms. Groce's echocardiogram; and Gerald L. Fitzgerald, Sr., the owner of the company that performed Ms. Groce's echocardiogram. In his affidavit, Dr. Brazil stated, in pertinent part, that:

> 10. Contrary to Paragraph 7 of Dr. Kisslo's declaration, I did not see excessive gain, color pixel dominance and the presence of color persistence or marked errors in the selection and measurement of jets and structures which would alter my original conclusions. Any errors made by the echocardiogram technician in tracing were slight and did not impact the ultimate diagnosis.
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> 11. And, contrary to Dr. Kisslo's finding, I did not find evidence of a concomitant use of decreased Nyquist settings or an exaggerated appearance of regurgitation and/or complicating factors. By Dr. Kisslo's own admission, the Nyquist setting in this instance was within the acceptable range (See Figure 5 on page 8 of Dr. Kisslo's declaration).
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> 12. I agree with Dr. Kisslo's statement that, "[s]ome of the hard controls, in particular color gain, image gain, and sector depth are adjusted to reflect the variability in patient physiology and attenuation as well as machine sensitivity normally encountered in imaging." My review of Ms. Groce's video tape and [magneto optical] disk indicates that the [sonographer] made adjustments during the course of the procedure to optimize the picture, not manipulate or materially misrepresent the injury sustained by Ms. Groce. Such adjustments are common in the ordinary course of conducting echocardiograms and I cannot see any evidence of any intentional material misrepresentation of fact as Dr. Kisslo and his staff suggest.

In her affidavit, Ms. Lollar-Goldstein stated she was familiar with the Settlement Agreement criteria and that each echocardiogram she performed was in accordance with that protocol and to the best of her ability. In addition, she noted that any adjustment she made to the echocardiogram machine settings during an echocardiogram "was done to optimize the image for the benefit of the doctor reading the procedure, not for the purpose of creating the false impression that an injury exists." Finally, Ms. Lollar-Goldstein stated that "virtually all echocardiograms will show some evidence of sparkling or excessive color gain if each frame is analyzed during the time the technician is making adjustments and attempting to optimize an image." In his affidavit, Mr. Fitzgerald stated that he always instructed his technicians to apply the Settlement Agreement criteria.

Claimant also argued that her echocardiogram demonstrated moderate mitral regurgitation. In his declaration, Dr. Brazil stated that he had reviewed Ms. Groce's echocardiogram and concluded that it "demonstrates that her regurgitant jet area is 25%, well within the moderate range ...." In addition, Ms. Groce noted that Dr. Brazil participated in the Trust's Screening Program.[7]

The Trust then issued a final post-audit determination, again denying Ms. Groce's claim. The Trust argued that claimant's contest failed to address adequately Dr. Kisslo's

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7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

findings of mismeasurements. The Trust also asserted that Dr. Brazil did not expressly deny the existence of improper machine settings but instead claimed only that he "did not see" the improper settings. In addition, the Trust contended that Ms. Groce misinterpreted Dr. Kisslo's illustration of available Nyquist levels as acceptable levels. Finally, the Trust contended that neither claimant nor her experts refuted Dr. Kisslo's findings with respect to the pattern of manipulation found in studies performed by the company that performed Ms. Groce's echocardiogram.

Claimant disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Groce's claim should be paid. On September 26, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7439 (Sept. 26, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, relying upon the arguments made in contest. On April 14, 2008, the Trust informed the Special Master that it intended to reply upon the documents previously submitted and the arguments that it had already raised. Under the Audit Rules, it

is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for her claim.[9] Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

9. Given our disposition with respect to claimant's level of mitral regurgitation, we need not determine whether there is a reasonable medical basis for finding that claimant suffered from one of the necessary complicating factors.

must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed Ms. Groce's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> The usual echocardiographic views were obtained. However, the study was not conducted in a manner consistent with medical standards. There was increased echo gain noted in all views. There was obvious excessive color gain causing color artifact within the myocardial tissue and outside of the heart. There was persistence with "stuttering" of cardiac images noted with systolic color images seen during diastolic echo images particularly in the apical views. An inappropriate[ly] low Nyquist limit of 41 cm per second was noted at a depth of 16.2 cm in the parasternal long axis view and 19.0 cm in the apical view. In addition, low velocity and non-mitral regurgitant flow was measured as part of the supposed RJA by the sonographer on this study. An off-axis view of the left atrium was used to inappropriately measure the LAA.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting

physician's finding that Ms. Groce had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

> A thin and short central jet of mitral regurgitation was noted in the parasternal long-axis view. Visually, very mild mitral regurgitation was noted in the apical four chamber and two chamber views. I digitized the cardiac cycles in the apical four and two chamber views. In spite of excessive echo and color gain as well as persistence and a low Nyquist limit, I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA in the apical four chamber view was 1.5 cm2. The largest RJA in the apical two chamber view was 1.7 cm2. I was able to accurately determine the LAA in this study. The LAA was 20.5 cm2. Therefore, the largest RJA/LAA ratio was 8%. Most of the RJA/LAA ratios were less than 5%. The RJA/LAA ratio never came close to approaching 20%. There was one supposed regurgitant jet area measured by the sonographer. This measurement was 3.80 cm2 taken in the apical four chamber view. This measurement was not representative of mitral regurgitation and included low velocity and non-mitral regurgitant flow at the beginning of systole and immediately after the QRS complex. This jet was a reflection of backflow and not mitral regurgitation. The sonographer measured the LAA to be 15.63 cm2 in the apical four chamber view. This measurement was inaccurate and taken in an off-axis view. The correct LAA was 20.5 cm2. The sonographer's inaccurate RJA and LAA determinations provide an RJA/LAA ratio of 24.3% which is a ratio close to the ratio of 25% documented by Dr. Brazil in his formal echocardiogram report.

In response to the Technical Advisor Report, claimant argues that there is no intentional material misrepresentation of fact because each cardiologist was able to evaluate the echocardiogram and that the differences among the readings "was simply the extent of the mitral valve regurgitation."

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. Groce had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante each found that claimant's sonographer improperly selected, traced and measured a supposed regurgitant "jet." According to Dr. Vigilante, "low velocity and non-mitral regurgitant flow was measured as part of the supposed RJA by the sonographer on the study." In addition, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram

settings included excessive color gain and an inappropriately low Nyquist to exaggerate the appearance of mitral regurgitation.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Groce's echocardiogram demonstrated, at most, only very mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Ms. Groce had moderate mitral regurgitation. Specifically, he explained that "the largest RJA/LAA ratio was 8%" and that "[m]ost of the RJA/LAA ratios were less than 5%."

Claimant does not substantively challenge the specific findings with respect to the manner in which her level of mitral regurgitation was evaluated. Dr. Brazil disputes that the inappropriate measurements of the sonographer influenced his determination of claimant's level of mitral regurgitation or that any inappropriate settings were used in performing Ms. Groce's echocardiogram, but he does not identify any particular error in the determinations of Dr. Kisslo or Dr. Vigilante that claimant's echocardiogram does not demonstrate moderate mitral regurgitation. A claimant cannot carry her burden when, like here, her expert merely states in conclusory fashion that the echocardiogram at issue does, in fact, demonstrate the requisite level of mitral regurgitation.[10]

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10. Thus, we reject claimant's argument that there is a (continued...)

We conclude, based on our review of the entire record, that there is no reasonable medical basis for Dr. Brazil's representation that claimant had moderate mitral regurgitation. Thus, we need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Groce's claim.[11]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will affirm the Trust's denial of Ms. Groce's claim for Matrix Benefits.

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10. (...continued)
reasonable medical basis for her claim simply because her attesting physician, Dr. Brazil, participated in the Trust's Screening Program.

11. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.